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Hemostatic Dressing Products for the Battlefield

Carl Snow
Cheryl Olson
Ted Melcer

Naval Health Research Center

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Naval Health Research Center
P.O. BOX 85122
San Diego, California 92186-5122

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Carl Snow[1]

Cheryl Olson[2]

Ted Melcer[2]

[1]MTS Technologies, Inc.
Arlington, VA 22206

[2]Naval Health Research Center
Medical Modeling, Simulation and Mission Support Program

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Summary

Problem

Uncontrolled hemorrhage is considered the major cause of death among warfighters. Various hemostatic dressings and other hemorrhage control products have been introduced or are in development specifically to treat combat casualties in the field. This review was part of tasking from the Office of Naval Research to review current alternatives for hemorrhage control.

Objectives

The objectives of the present report are to:

- provide an assessment of current and developing hemostatic dressing products or methods with military potential
- provide a summary table of current published research on these products or methods

Approach

The Medical Modeling, Simulation and Mission Support program at Naval Health Research Center initiated a “Tech Watch” project to investigate current and developing technologies. The Tech Watch team develops investigative reports based on Internet searches for candidate product solutions such as hemostatic dressings and independently published research evaluating these products.

Results

A variety of hemostatic dressing products are currently available, and several have been used in the field with some success. The various advantages and disadvantages of each product are presented in the main text of this report. At present, no one product appears to offer a complete solution, and most remain under continual development to reduce cost or side effects, increase usability, and/or meet specific combat care niches such as for major versus minor wounds.

Recent developmental projects target noninvasive methods to control bleeding, such as ultrasound or medication.

Conclusion

Hemorrhage control in combat settings is an active and important area of military medical research. Some products have been fielded and show promise, but considerable work is needed to refine them. The niche for products by wound types also needs to be addressed.

Introduction

For soldiers wounded on the battlefield, hemorrhage control is essential to survival. Uncontrolled hemorrhage is the primary cause of death in the pre-hospital period for both military combat and civilian trauma incidents. Immediate action is highly effective in limiting patient mortality, since most bleeding fatalities occur within the first 30 minutes of the injury. It is generally accepted that hemostatic products for forward care in the battle zone must control bleeding quickly, be ready to use, simple to apply for first responders in combat situations, have a shelf life approaching 2 years, and prevent bacterial or viral transmission (Alam, Burris, DaCorta, & Rhee, 2005; Pusateri, Modrow et al., 2003).

Those surviving severe injury have increased not only in a warfare environment, but also in a nonbattle emergency trauma environment with the help of innovative techniques and products that control and or stop bleeding as quickly as possible. Hemorrhage control technology has developed a variety of procedures, techniques, and products that stem or halt the flow of internal as well as external bleeding. The U.S. military uses some of the currently available hemorrhage control products on the battlefield and at field medical treatment facilities (MTFs).

Objectives and Methods

The Navy Technology Watch investigated and reported on methods and products that advertise hemorrhage control by searching the Internet, online publication databases, and brief telephone interviews with relevant investigators in the field, vendors, or Department of Defense (DoD) officials.

The requirements for a hemorrhage control products are not easily specified due to the diversity of combat injuries that cause traumatic bleeding, such as blunt trauma, blast wounds,

lacerations and/or penetrating injuries. Also, the products must be applied in austere combat environments by first responders or wounded soldiers who can only carry a limited supplies (Alam et al., 2005). The product should work rapidly and avoid complicating later treatment such as surgery. Products such as gauze dressings with ingredients from a variety of sources that facilitate control of external bleeding may be most useful to first responders. The most critical wounds are those for which a tourniquet or simple compression are not feasible, such as internal bleeding in the chest, abdomen, and pelvis, and closed extremity fractures that are not easily accessible. Therefore, internal bleeding usually requires rapid surgical intervention. Recent development efforts discussed below have investigated noninvasive methods, such as medications and ultrasound, that may locate and control severe internal bleeding (Basu, 2004).

Most military medical personnel agree that use of candidate products in combat situations cannot wait for ideal data, such as randomized clinical trials with human patients (Alam et al., 2005). The practical approach is to provide subject matter experts with the best available data, usually from animal models, and consideration of battlefield requirements. Subject matter experts can then develop a consensus for which products should be fielded for combat casualty care. The present report provides a summary of recent products and their strengths and weaknesses.

Until recently, first responders were limited to techniques that have not changed for decades: direct pressure, elevation, and tourniquets where possible, until the victim could receive fluid resuscitation and surgical repair of the wounds (Cloonan, 2004). These techniques may be inadequate when wounds are in areas where compression and tourniquets cannot be applied, and the Combat Casualty Care Research Program has made the development of alternative, effective hemostatic dressings usable by first responders a priority (Pusateri, et al., 2003). This initiative

has contributed to the development of dressings and hemostatic agents, making use of a variety of ingredients.

Each type has strengths and weaknesses, which bear on its feasibility for military use. The present review will examine the available research testing and comparing hemostatic products.

The objectives were to describe the available products per vendor claims and to:

- Underscore the pros and cons of each product
- Identify applicability to military environment
- Note adverse effects, reliability, and cost issues
- Provide a summary table of independently published research

Results

The results present information on how the products work and the products themselves, and a summary of a recent literature review of laboratory animal and other published studies on these products.

Current Methods

Current methods of wound intervention include absorbent pads containing clotting agents, topically applied clotting or bleeding-cessation agents in powder or granule form, pressure bandages, gauze, tourniquets for extremities, and trauma kits for wounds to the body. These products meet a crucial need for both military and civilian casualties at the point of injury before evacuation, when time is critical. While they differ in composition and ingredients, external bleeding cessation agents all work to help the rapid formation of a thrombus (clot) or other blockage at the site of application. Clotting products generally contain high concentrations

of materials such as human fibrinogen, thrombin, calcium, factor XIII, and antifibrinolytics. A popular bandage, developed jointly by the Army and the Red Cross, uses fibrin to mimic the final stages of blood coagulation. Although these components are naturally present in every wound, the fibrin hemostatic product supplies the clotting agents faster and in a much higher concentration than the body does, leading to faster clot formation. In addition to fibrin, other available hemostatic agents in use are microporous polysaccharide hemosphere, mineral and synthetic zeolite, and poly-N-acetyl glucosamine, a shellfish derivative usually referred to as chitosan.

Developmental Methods

Researchers are seeking to develop new methods to prevent warfighters from becoming bleeding casualties. The Army's Combat Casualty Care Research Program at Fort Detrick, MD, includes work with physiologic sensors, blood products, dental injury and disease, surgical techniques, brain and spinal injuries, and survival strategies prior to evacuation (Basu, 2004). In addition to clotting by means of exterior devices, Basu has described the relatively new frontier of battle area medical studies focused on noninvasive techniques, such as drugs and ultrasound. Up until now, the only course of action has been surgery. For chest and abdominal bleeding, recent research has addressed three areas: hemostatic foam; high-intensity, focused ultrasound; and recombinant activated factor VII, which is a genetically engineered version of a naturally occurring human blood clotting factor. However, most Army research into internal hemorrhage control has shifted to this third area of recombinant activated factor VII. This solution was previously developed for hemophiliacs to induce blood clotting. This method has been used on about 300 hospital patients in Israel after anecdotal evidence of its initial success in seriously wounded patients. In the field, it could add hours to survival time before evacuation. At present,

none of these three solutions is suited for use by far-forward troops because of present size of the equipment needed, training issues, and lack of FDA approval. For the first two solutions, application is still too complex to be practical for first responders and combat lifesavers.

Product Reviews

For the purposes of hemostatic response in the field, products discussed during this investigation will concentrate on external utilization. The following products were evaluated by type of hemostatic agent, application methodology, cost considerations, and possible adverse effects. Vendor contact information is summarized in Appendix A.

Chitosan. Chitosan is a biodegradable, nontoxic, complex carbohydrate of chitin, is found in the exoskeletons of shellfish. It will not cause an allergic reaction, according to product literature. A recent study by the U.S. Army Institute of Surgical Research looked at the effectiveness of a chitosan-based hemostatic dressing to prevent blood loss in swine. Based on the results, the team concluded that a chitosan dressing reduced hemorrhage and improved survival after severe liver injury in swine and that further studies are warranted. The bandage is designed for immediate hemorrhage control and is deployable by an injured soldier, combat medic, or an untrained first responder. The U.S. Army and other laboratories have tested the bandage on animal models of severe bleeding.

Product: HemCon Bandage; HemCon Medical Technologies, Inc., Portland OR

Chitosan based

Military Interest: USA

Price: Approx. $100 per 4 x 4 bandage

HemCon Inc. has received $19 million in military funding for research and development, manufacturing expansion, and product procurement. Currently, the dressings have a shelf life of 18 months, but HemCon hopes to lengthen that to 24 months with further development. Approximately 75,000 HemCon dressings have been shipped to U.S. forces thus far. DoD and other government agencies have placed orders for an additional 30,000 dressings.

Pros	Cons
Effective clotting agent	High cost
Absorbable material	Short shelf life
Bacteriostatic effect on wound	Competitors report potential allergic reaction
No adverse side effects reported	
Supported by U.S. Army	

Zeolite. Granular zeolite is a substance derived from lava rocks. When this material is placed into a bleeding wound, it absorbs the water molecules in the blood and creates a high platelet concentration to promote clotting. This causes an exothermic reaction. Several U.S. Navy physicians who served in Iraq report that this substance produces sufficient heat to cause burns to the skin if measures are not taken to wipe off water, sweat, and excess blood from the wound and skin before use. In fact, Navy Corpsmen who served with Marine combat units in Iraq reported they observed "second-degree burns" in Iraqi soldiers treated with this type of hemostatic methodology.

Product: QuikClot; Z-Medica Corporation, Wallingford, CT

Zeolite based

Military Interest: U.S. Marine Corps

Price: Approx. $22 per package

QuikClot was originally developed in 1989 and has been used primarily in the Marine Corps individual first-aid kit, and more than 350,000 units have been sent to Iraq.

Pros	Cons
Long shelf life	Nonabsorbable; distorts anatomy of wound
Low cost	Can cause second-degree burns if not applied correctly
Effective clotting agent	Contraindicated for internal bleeding or deep tissue wounds

Collagen. Collagen-like natural substances are created from chemically treated cellulose. When they come in contact with blood, they expand to 3-4 times their original size and convert to a gel that dissolves into glucose and saline over a 1-2 week period. These materials contain no chemical additives, thrombin, or actual collagen, and they are hypoallergenic. Because of their purity and the fact that they simply degrade to these end products, they do not cause delayed healing as do other hemostatic materials that may have a similar appearance. Collagen-like natural substances can effectively cut down on clotting time, help stabilize new clots by accelerating the formation of fibrin cross-linkages, and increase whole blood viscosity, thereby

potentially promoting red blood cell aggregation. The earlier products of this type were commonly referred to as Gelfoam and were used extensively during surgical procedures.

Product: ActCel Hemostatic Gauze; ActSys Medical, Inc., Westlake Village, CA

Collagen based

Military Interest: Under consideration by the Office of Naval Research

Price: Approx. $6 per bandage

ActCel, which is in a fabric-like state, increases platelet adhesion, thereby promoting clotting. This is similar to adherence of platelets to damaged collagen (the fibrous protein found in connective tissue that underlies the endothelial cells). ActCel stops bleeding quickly and effectively by adhering to the bleeding surface, physically blocking and sealing off the damaged blood vessels, expands to create direct pressure, transforms into a collagen-like gel that increases platelet aggregation and stabilizes clot formation, and is easily rinsed away with sterile water, saline, or hydrogen peroxide. Once ActCel has helped form a clot, it will dissolve into a glucose saline gel in 1-2 weeks (Bone, 2005).

Pros	Cons
Cost effective	Minor or moderate trauma use
Dissolves into saline/glucose over time; does not interfere with later treatment	Limited test data to date
Hypoallergenic; no reported side effects	
Quick clotting time; bacteriostatic	

Product: Surgicel; Ethicon, INC.., Piscataway, NJ 08855

Collagen based

Military Interest: General surgical

Price: Approx. $18 per ½ inch x 2 inch bandage; cost increases with size

Surgicel is primarily utilized for hemostatic wound management during surgical procedures. It has the ability to wrap around large vessels and stop severe bleeding during cardio and vascular procedures. In addition, the Surgicel product line has developed a variety of hemostatic materiel that ranges from a fiber-like substance to a liquid collagen and fibrin mixture for hard-to-reach direct applications. Surgicel is manufactured by the original makers of Gelfoam, which was an earlier hemostatic product utilized during surgery in the 1970s, ’80s, and early ’90s.

Pros	**Cons**
Versatility; trauma and general surgery use	Not specifically a trauma product
Absorbable	Fibrous component may not degrade rapidly and may cause complications

Algae based. Algae-based coagulants primarily stimulate the body to produce its own coagulants (Paul & Sharma, 2004). This stimulates platelet activation, which leads to the secretion of a substance known as thromboxane. Thromboxane stimulates the constriction of blood vessels near the wound, which helps slow blood flow there. These types of bandages are excellent for extremity wounds, most notably traumatic amputations. The properties of this

coagulant allows a gelatin-like formation in the wound. As a result, bandages of this type prevent further trauma, pain, and hemorrhage due to their nonadherence. They provide a moist environment that leads to rapid granulation and re-epithelialization. In addition, algae-based coagulant properties are useful in split-thickness skin grafts required for burn patients. It is also excellent for applying these bandages on actual burn sites to promote healing.

Product: Rapid Deployment Hemostat (RDH); Marine Polymer Technologies, Danvers, MA 01923

Algae based

Military Interest: Office of Naval Research

Price: 4 x 4 bandages; price at market negotiation

RDH uses a material called poly-N-acetylglucosamine to promote blood clotting. This substance comes from a single cell algae originating from the ocean.

Pros	Cons
Excellent for extremity and burn trauma	Price fluctuation
Can be used for surgical procedures	Availability may be limited
Absorbable	

Potato starch based. The potato starch coagulant base is derived by synthesizing a substance called microporous polysaccharide hemosphere. When applied directly with pressure to an actively bleeding wound, the particles accelerate natural blood clotting by concentrating

blood solids such as platelets and red blood cells, and other blood proteins such as albumin, thrombin, and fibrinogen, to form a gel around the particles. This material creates a high concentration of platelets, thrombin, fibrinogen, and other proteins on the particle surface, producing a gelling action. The gelled, compacted thrombin and fibrinogen cells accelerate the normal clotting process. This gelling process has been shown to initiate within seconds. Primarily it is intended for the temporary treatment and management of severe bleeding while in transit to a field MTF, hospital, or trauma center.

Product: TraumaDEX; Medafor, Inc., Minneapolis, MN 55430

Potato starch based

Military Interest: None known

Price: $25 per 5 grams

TraumaDEX is in powder form and is applied directly to the bleeding wound via a bellows applicator. TraumaDEX does not cause an exothermic reaction, so there is no risk of secondary burns to the skin like those experience with QuikClot. Also, unlike QuikClot, TraumaDEX is reabsorbed naturally by the body within hours and does not need to be washed out of the wound prior to definitive wound repair.

Pros	Cons
Absorbable, biocompatible; no exothermic reaction	Cannot be used for internal bleeding
Low cost	Must remove excess blood before application
Package easily stowed	Must apply direct pressure post-application

Hydrophilic polymer and potassium salt with bovine-based thrombin material. The hydrophilic polymer absorbs the water from the blood, causing the polymer to swell. The potassium salt serves as a binding agent to form a protective scab. The bovine-based coagulants stimulate blood clotting. This instant artificial scab adheres to the wound bed, seals and protects the wound, and enables the body's natural healing process to begin immediately.

Product: UrgentQR (Quick Relief); Biolife, LLC, Sarasota, FL 34243

Hydrophilic polymer based

Military Interest: None known

Price: $2 for a 30-blister package

According to company literature, Biolife's initial core brand is QR (Quick Relief) Powder, a wound dressing and highly cost-effective topical powder that stops bleeding instantly. It also acts as a protective barrier and bactericide to protect wounds. There are several other products, each with a specific use. For example, SuperQR is for major or severe

wounds, UrgentQR is for minor wounds, NosebleedQR is for hydrophilic polymer nosebleeds, and OralQR is for oral wounds and to stop bleeding due to oral surgery and tooth extractions. Biolife product literature states a 96% success rate in an ongoing clinical study treating lacerations, nosebleeds, skin tears, punctures, and abrasions. Normally, for minor wounds, no covering bandage is required.

Pros	Cons
Reasonable cost	Superficial to moderate hemorrhage
Addresses ear/nose/throat (ENT) and dental bleeding	Blister packs may not be suitable for tactical environment
Absorbable	Alternative packaging may be problematic
Instantly creates protective scab	

Dry fibrin sealant dressing (DFSD). This type of dressing is in an experimental phase. As indicated by its name, this dressing material is composed of dry fibrin (Travis, 1999). It comes in a powder form and can be applied directly to the bleeding. The dry fibrin sealant dressing is currently being evaluated for arterial bleeding associated with internal hemorrhage. Initial studies appear encouraging. The dressing was applied to arterial bleeding under a controlled environment utilizing pigs for the experiment. Studies showed immediate coagulation of arterial bleeding associated with liver trauma and other internal trauma scenarios compared with conventional methods of hemostasis.

Product: Dry fibrin sealant dressing (DFSD); U.S. Army Institute of Surgical Research, Fort Sam Houston, TX 78234-6315

Dry fibrin based

Military Interest: U.S. Army (experimental)

Price: Not applicable at present

In a 1-hour study, DFSD controlled exsanguinating hemorrhage from a large arterial injury as well as sutured repair. DFSD may provide hemorrhage control for exsanguinating extremity injuries until definitive repair.

Pros	Cons
Developmental product for internal bleeding	Unable to assess at this time

Literature guide. We also reviewed current literature and summarized products tested and study details in the table below as a quick reference guide.

Table 1. Summary of Research and Reviews for Hemostatic Products

Product(s)	Reference	Study Type	Wound Types	Outcomes
RDH, QuikClot	Alam et al. (2003)	Experimental (swine)	Complex groin injury, arterial, venous	QuikClot produced 0% mortality; RDH had a 66% mortality rate.
QuikClot	Alam et al. (2004)	Experimental (swine)	Partial thigh transection, femoral artery and vein	QuikClot achieved 100% survival.
RDH, HemCon, QuikClot	Alam et al. (2005)	Review	N/A	QuikClot: effective but with side effects RDH: Inconsistent efficacy HemCon: Promising but difficult to standardize
HemCon, DFSD, QuikClot	Cloonan (2004)	Review	N/A	DFSD: Effective but costly QuikClot: Effective with proper training HemCon: Reports from field mostly favorable
HemCon prototype	Cole et al. (1999)	Experimental (swine, human)	Multiple spleen incisions and stripping (swine); bowel incision (human)	Outperformed oxidized cellulose in achieving hemostasis in both studies.
DFSD	Holcomb et al. (1997)	Review and partial data (swine)	Grade V liver injury	New fibrin dressings are safe and can be standardized. Data show efficacy in swine model.
DFSD	Holcomb et al. (1998)	Experimental (goats)	Ballistic injury to extremity; femoral artery and vein	All subjects survived, but DFSD was superior in reducing blood loss and maintaining blood pressure.
DFSD	Holcomb Pusateri, et al (1999)	Experimental (swine)	Grade V liver injury	Blood loss with DFSD was 51% of loss with gauze control dressing.
DFSD	Holcomb, Pusateri et al. (1999)	Experimental (swine)	Grade V liver injury; coagulopathy	DFSD improved survival, decreased fluid requirements, and controlled hemorrhage rapidly.
RDH	Jewelewicz et al. (2003)	Experimental (swine)	Severe liver injury; coagulopathy	Survival rate at 3 hours was 80% for RDH vs. 0% for standard packing.

Product(s)	Reference	Study Type	Wound Types	Outcomes
Chitosan, fibrin	Kheirabadi et al. (2005)	Experimental (swine)	Infrarenal artery	RDH-type (chitosan) failed at 1.6 hours after hemostasis. DFSD-type (fibrin) was successful in 5/6 cases.
DFSD, QuikClot; HemCon	King et al. (2004)	Review	N/A	All have only anecdotal support in combat. Fibrin is most effective, but may be fragile. QuikClot did well in lab tests, but combat data are needed.
QuikClot, DFSD, RDH, HemCon	McManus & Wedmore (2005)	Review	N/A	QuikClot: Requires training to use safely DFSD: Durability may be a problem RDH: Effective but not widely available HemCon: Problems with variability leading to some failures
Chitosan prototype	Pusateri, McCarthy et al. (2003)	Experimental (swine)	Severe venous injury; hepatic injury	Dressing significantly improved survival rate and hemostasis over gauze.
9 dressings, including DFSD, HemCon	Pusateri, Modrow et al. (2003)	Experimental (swine)	Severe venous injury; hepatic injury	Only DFSD showed a survival rate significantly greater than gauze
Salmon fibrin prototype	Rothwell et al. (2005)	Experimental (swine)	Aortotomy	All fibrin-treated animals survived, compared with a 7/8 death rate in controls treated with standard gauze.
10 dressings, including DFSD	Sondeen et al. (2003)	Experimental (swine)	Aortotomy	Only DFSD was effective, equal to suture.
RDH	Vournakis et al. (2003)	Experimental (swine)	Aortotomy	80% survival with RDH, compared with 40% with Army field bandage.
HemCon	Wedmore et al. (2006)	Survey (combat medical personnel)	Various, including 4 arterial	Retrospective survey found HemCon controlled bleeding in 95% of cases.
QuikClot	Wright et al. (2004)	Case study (civilian)	Multiple gunshot wounds	QuikClot controlled bleeding in spite of severe coagulopathy.
QuikClot	Wright, Kalns et al. (2004)	Experimental (swine)	Skin, muscle, liver, spleen, femoral artery, femoral vein	Application of QuikClot resulted in thermal injury and necrosis of wound sites.

Conclusions

There are a variety of coagulant dressings on the market that can perform up to optimal standards and integrate well into the military's trauma and field medical materiel. However, the most noticeable characteristic is that not all coagulant dressings are the same. It is not merely a matter of one dressing being better than another. Some dressings are predominantly for extremity wounds; some perform better with burn trauma; some have the ability to control hemorrhage in hard-to-reach areas, such as mouth, dental, and ENT regions; some treat superficial wounds; and some have the ability to curtail internal bleeding. But no one dressing can do it all.

Therefore, to fully determine optimal hemorrhage control product performance, the simple solution of "one size fits all" may not be the answer. The information in this report provides a comprehensive list of coagulant products that the U.S. military medical community can evaluate and determine, based upon need, priority, and cost, which products will provide the best possible solutions for traumatic hemorrhage control in a battlefield environment.

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Appendix A

Product Information

ActSys Medical, Inc.
31186 La Baya Drive, Suite #100, Westlake Village, CA 91362
Phone: 1-800-808-9094, fax: 1-818-707-9094, e-mail: info@actsysmedical.com
Web site: http://www.actcel.com

Biolife, LLC
c/o Customer Care Department
1235 Tallevast Road, Sarasota, FL 34243
Phone: 1-800-722-7559, fax: 1-800-204-1115
Web site: http://www.biolife.com

HemCon Medical Technologies, Inc.
10575 SW Cascade Avenue, Suite 130, Portland, OR 97223
Phone: 503-245-0459, fax: 503-245-1326, e-mail: info@hemcon.com

Marine Polymer Technologies
107 Water Street, Danvers, Massachusetts 01923
Phone: 781-270-3200

Medafor, Inc.
2700 Freeway Boulevard, Suite 800, Minneapolis, MN 55430
Phone: 1-877-MEDAFOR, fax: 763.571.1035, e-mail: info@medafor.com

Z-Medica Corporation
4 Fairfield Blvd. Wallingford, CT 06492
Phone: 203-294-0000, fax: 203-294-0688
Web site: www.z-medica.com

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6. AUTHORS
Carl Snow, MTS Technologies, Inc.; Cheryl Olson, Ph.D., MTS Technologies, Inc.; Ted Melcer , Ph.D., Naval Health Research Center

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Naval Health Research Center
P.O. Box 85122
San Diego, CA 92186-5122

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Commanding Officer
Naval Medical Research Center
503 Robert Grant Ave
Silver Spring, MD 20910-7500

Commander
Navy Medical Support Command
PO Box 240
Jacksonville, FL 332212 0140

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Ted Melcer , Ph.D., Principal Investigator

14. ABSTRACT (maximum 200 words)

Uncontrolled hemorrhage is the major cause of death among warfighters. Hemostatic dressing products have been introduced to treat combat casualties in the field. The objectives of the present report are to provide an assessment of current and developing hemostatic dressing products or methods with military potential, and to provide a summary table of current research evidence on these products or methods. The Medical Modeling, Simulation and Mission Support program at Naval Health Research Center initiated a “Tech Watch” project to investigate current and developing technologies for hemostatic dressings and to review current independently published research evaluating these products. A variety of hemostatic dressing products are currently available, and several have been used in the field with some success. A summary of each product is presented in the main text of this report. At present, no one product appears to offer a complete solution, and most remain under continual development to reduce cost or side effects, increase usability, and/or meet specific combat care niches such as for major versus minor wounds. Recent developmental projects target noninvasive methods to control bleeding, such as ultrasound or medication.

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